MAY - 2 2000

K 000663

510(K) SUMMARY
as required by 807.92(c)

K000663

KRONNER PROTOTYPES, INC.

1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97470
Phone: (541) 672-2543
FAX: (541) 672-1074
E-mail: kronner@rosenet.net

Prepared: February 22, 2000

Contact Person: Richard Kronner, President

K000663

Trade Name: **Kronner Low Profile Scope Holder**

Common Name: **Endoscope Holder**

Classification Name: **Endoscope holding device**
(no industry name for this device)

K000663

Equivalent to legally marketed devices

by

(K973543) Kronner Prototypes, Inc.

K000663

Description:

The Kronner Low Profile Scope Holder with Electronic Control and Control Box is the same as the Kronner Low Profile Scope Holder (K973543) with mechanical control except that it has an electronic control, momentary button, and electronic control box with solenoids to control gas output.

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Intended Usage:

KSH-4 Kronner Low Profile Scope Holder

For abdominal and thoracic endoscopic surgical procedures

HPL2-CRL High pressure* Gas Line Set

For abdominal and thoracic endoscopic and arthroscopic surgical procedures

KSHSA-3 Standard Arm Assembly

For abdominal and thoracic endoscopic surgical procedures

C-1 Control

For abdominal, thoracic, arthroscopic, endoscopic surgery and holding manual surgical instruments

ECB-2 Electronic Control Box

For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

GLW-1 Gas line wrench

For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

SEAH-1 Small Endoscope Accessory with Handle

For nasal endoscopic surgical procedures

HPL1-BL1-CRL High pressure* Branched Gas Line Set

For nasal endoscopic surgical procedures and holding manual surgical instruments

* Tolerates pressures to 150 PSI, do not use with pressures over 150 psi.

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Summary of technological characteristics of device compared to predicate devices.

The Kronner Low Profile Scope Holder with Electronic control and Electronic Control Box is essentially equivalent to the Kronner Low Profile Scope Holder (K973543) except that the mechanical control has been replaced with an electronic control and electronic control box with solenoids to control gas output.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Richard F. Kronner, M.D.
President
Kronner Prototypes, Inc.
1443 Upper Cleveland Rapids Road
Roseburg, Oregon 97470

Re: K000663
Trade Name: Low Profile Scope Holder
Regulatory Class: II
Product Code: KOG, GCJ
Dated: February 22, 2000
Received: February 28, 2000

Dear Dr. Kronner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): _____K000663_____

Device Name: Kronner Low Profile Scope Holder

Indications for Use:

KSH-4 Kronner Low Profile Scope Holder
For abdominal and thoracic endoscopic surgical procedures

HPL2-CRL High pressure* Gas Line Set
For abdominal and thoracic endoscopic and arthroscopic surgical procedures

KSHSA-3 Standard Arm Assembly
For abdominal and thoracic endoscopic surgical procedures

C-1 Control
For abdominal, thoracic, arthroscopic, endoscopic surgery and holding manual surgical instruments

ECB-2 Electronic Control Box
For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

GLW-1 Gas line wrench
For abdominal, thoracic, arthroscopic, nasal endoscopic surgical procedures and holding manual surgical instruments

SEAH-1 Small Endoscope Accessory with Handle
For nasal endoscopic surgical procedures

HPL1-BL1-CRL High pressure* Branched Gas Line Set
For nasal endoscopic surgical procedures and holding manual surgical instruments

* Tolerates pressures to 150 PSI, do not use with pressures over 150 psi.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anne R. Vachon

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000663

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-The-Counter Use _____

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(Optional Format 1-2-96)